

## Actions Taken by FDA Center for Veterinary Medicine

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The following corrections or additions to the January 15 1998 list were made in January 1998

### New Approvals

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**ANADA Number: 200-167**

Pioneer Product: 039-077  
Trade Name : Aureozol 500 Granular  
Ingredients: Chlortetracycline calcium complex, sulfathiazole, penicillin procaine  
Sponsor: Hoffmann-La Roche, Inc.  
Approval Date: 01/15/98  
Status: Over-the-counter  
Route: Oral  
Species: Porcine  
Drug Form: Type A medicated article  
Concentration: CTC calcium complex equivalent to CTC HCl: 40 g/lb  
Sulfathiazole: 40 g/lb  
Penicillin: 20 g/lb  
Indications: Pre-Starter and Starter Feeds: for reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibronic dysentery); maintenance of weight gain in the presence of atrophic rhinitis; increased rate of weight gain and improved feed efficiency from 10 pounds of body weight to 6 weeks post-weaning. For swine raised in confinement (dry lot) or on limited pasture.  
Grower and Finisher Feeds: for reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibronic dysentery); maintenance of weight gain in the presence of atrophic rhinitis; increased rate of weight gain from 6 to 16 weeks post-weaning. For swine raised in confinement (dry lot) or on limited pasture.  
Tolerance: 21CFR 556.690: Sulfathiazole: 0.1 ppm for negligible residues in the uncooked edible tissues of swine.  
21CFR 556.510: Penicillin: Zero in the uncooked edible tissues of swine.  
21CFR 556.150: Chlortetracycline: 12 ppm in fat and kidney, 6 ppm in liver, and 2 ppm in muscle.  
Withdrawal: 7 days.  
*21CFR 558.155*

### Supplemental Approvals

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**NADA Number 140-921**

Trade Name : Prednis Tab  
Ingredients: Prednisolone  
Sponsor: Lloyd, Inc.  
Approval Date: 11/20/97  
Status: Prescription only  
Route: Oral  
Species: Canine  
Drug Form: Tablet  
Concentration: 20 mg/tablet  
Indications: Anti-inflammatory agent

This supplemental application provides for an additional tablet strength of 20 mg prednisolone. The approved tablet strength is 5 mg prednisolone.

*21CFR 520.1880*